UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

SCOTT ALLEN MILLER
and TINA MILLER,

Plaintiffs,

v.

RUSH UNIVERSITY MEDICAL CENTER, DR. HAREL DEUTSCH, DR. ANTHONY M. ALVARADO, ZIMMER BIOMET SPINE, INC., ZIMVIE, INC., HEALTHWERKS, INC., SAM CLARK, and CARL CORSI,

Defendants.

Case No. 23-cv-02210

Judge John Robert Blakey

MEMORANDUM OPINION AND ORDER

Plaintiffs, Scott Miller and Tina Miller, have sued Rush University Medical Center, Dr. Harel Deutsch, and Dr. Anthony M. Alvarado (collectively the "Rush Defendants") along with Zimmer Biomet Spine, Inc., ZimVie, Inc., Healthwerks, Inc., Sam Clark, and Carl Corsi (collectively the "Manufacturer and Distributor Defendants"), alleging medical negligence, negligence, lack of informed consent, product liability, and loss of consortium arising out of Scott Miller's September 13, 2022 surgery at Rush University Medical Center. *See* [84].

The case comes before the Court on Defendants' motions to dismiss Plaintiffs' Third Amended Complaint ("TAC"). [93], [96]. For the reasons explained more fully below, the Court grants in part, and denies in part, the motions to dismiss.

I. Background

A. Factual Background

Plaintiff Scott Miller sought treatment at Defendant Rush University Medical Center in July 2022 for arm and neck pain. [84] ¶ 137. Following an MRI examination, Defendant Dr. Harel Deutsch, Miller's physician, recommended that Miller undergo a C5-6 and C6-7 cervical disc replacement. *Id.* ¶ 139. Deutsch performed the surgery on September 13, 2022, with the assistance of Defendant Dr. Anthony Alvarado. *Id.* ¶¶ 140–42. The surgery involved the use of a Zimmer Biomet Spine Mobi-C Cervical Disc Replacement device ("Mobi-C"). *Id.* ¶ 149. The Mobi-C device functions as a device "for cervical intervertebral disc replacement." *Id.* ¶ 68. Plaintiffs allege that, during Scott Miller's surgery, the surgeons implanted the Mobi-C device too deep at disc C5-6 as the result of a failed depth stop, causing Miller to suffer a spinal cord contusion. *Id.* ¶¶ 101, 151–52.

The Medical Device Act ("MDA") regulates medical devices and categorizes medical devices into three classes—Class I, Class II, and Class III—based upon the risk posed to the public. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315, 316–17 (2008). A Class III device must receive "premarket approval to provide reasonable assurance of its safety and effectiveness." 21 U.S.C. § 360c (a)(1)(C). Premarket approval ("PMA") is an extensive process. *Id.* § 360e; *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996) (noting that the "'PMA' process is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which

the FDA then reviews, spending an average of 1,200 hours on each submission."). A PMA application includes "information relating to intended use, safety studies and test results, principles of operation, descriptions and specifications of components, a description of intended manufacturing methods, facilities and controls, packing, proposed labeling, and installation." *Isbell v. Medtronic Inc.*, 97 F. Supp. 2d 849, 851 (W.D. Tenn. 1998); 21 U.S.C. § 360e(c)(1). Following approval, the device can only enter the market consistent with the specifications approved by the FDA. 21 CFR § 814.80. In other words, unless the FDA approves a modification, the information in the PMA application constitutes the legal requirements that the device must follow. Changes to the device can occur through the approval of a PMA supplement, a process similar to the approval process for the original PMA. 21 C.F.R. § 814.39.

The Mobi-C device received premarket approval from the FDA on August 23, 2013, as a Class III medical device. [84] ¶ 62. The PMA required the Mobi-C device to conform with approved specifications from the FDA. [97-1]. The product instruction manual, approved through the PMA, described the Mobi-C device:

> The Mobi-C® Cervical Disc Prosthesis (Mobi-C®) is a single use device for cervical intervertebral disc replacement at one level from C3 to C7 in order to maintain/restore segmental motion and disc height. The components of the Mobi-C® include a cobalt, chromium, molybdenum (CoCrMo per ISO 5832-12) alloy superior spinal plate, an inferior CoCrMo spinal plate, and an ultra-high molecular weight polyethylene (UHMWPE per ISO 5834-2) mobile insert. The inner contact surfaces of the superior and inferior spinal plates are spherical and flat, respectively. This allows for fully congruent contact surfaces between the spinal plates and mobile insert. The two lateral stops of the inferior plate control and limit the mobility of the mobile insert. The spinal plates, both superior and inferior, feature two rows of teeth to allow for

> initial and long term fixation and stability. The teeth sink into the bone to facilitate endplate fixation and do not require any bone removal or chiseling prior to insertion. The Mobi-C has a bone sparing design and technique. A titanium (per ASTM F1580) and hydroxyapatite (per ISO 13779) plasma spray coating is applied to the bony interface surfaces of the superior and inferior spinal plates.

[84] ¶ 68; *see also* [97-4] at 28. The PMA notice of approval required that the Mobi-C labeling note the specific training or experience necessary for practitioners to use the device. [84] ¶ 71. The Mobi-C PMA also required specific instructions for use, product warnings, instrument testing protocol, and handling instructions. *Id.* ¶¶ 72–74.

Mobi-C has since received several supplemental approvals modifying the original PMA. [97-3]. These modifications included an approval on February 5, 2015, for "modifications made to the Mobi-C universal inserter instrument," *id.* at 2–5, approval on March 3, 2017, for "kitting and shipping of new components as well as reconditioning and servicing of used instruments from the field of use," *id.* at 11–13, and approval on November 13, 2019, for "a new manufacturing site to be used for kitting and shipping of Mobi-C as well as reconditioning and servicing of instruments from the field of use." *Id.* at 17–19. Other supplemental approvals addressed modifications to the Mobi-C labeling and surgical technical manual. *Id.* at 5–7, 8–10.

The Mobi-C device uses a Universal Inserter/Implant Inserter ("inserter") to place the Mobi-C disk during surgery. [84] ¶ 86. After 2009, the inserter included a "depth stop" or "stop" mechanism to prevent the device from going too far into the spinal cord during implantation. *Id.* ¶¶ 87, 88. The Mobi-C product instruction manual includes steps for setting up the depth stop, loading the implant into the

inserter, and controlling the depth of the device. *Id.* ¶¶ 90, 91.

Defendants Zimvie, Inc. and Zimmer Biomet Spine, Inc. (collectively, the "Manufacturer Defendants") manufacture and design the Universal Inserter/Implant Inserter used with the Mobi-C device. Defendant Healthwerks distributes the product, and Defendants Sam Clark and Carl Corsi (collectively the "Distributor Defendants"), were product representatives for the Mobi-C device on behalf of Healthwerks, who were present at Miller's surgery. *Id.* ¶ 148. Plaintiff alleges that Clark and Corsi maintained responsibility for verifying that the Mobi-C implanter was appropriately used, set up, assembled, and/or loaded during surgery, *id.* ¶¶ 273, 289, and that the surgical team at Rush University Medical Center relied on Clark and Corsi for this purpose. *Id.* ¶¶ 272–74, 288–90. Nothing in the Mobi-C product manual indicates that sales representatives have a role in surgery; and the surgical technique guide instead states that the "document is intended exclusively for physicians." [97-4] at 33.

B. Procedural Background

On March 22, 2023, Plaintiffs sued Rush University Medical Center, Dr. Harel Deutsch, and Dr. Anthony M. Alvarado (collectively, the "Rush Defendants") along with Zimmer Biomet Spine, Inc., ZimVie, Inc., Healthwerks, Inc., Sam Clark, and Carl Corsi in the Circuit Court of Cook County, Illinois. Zimmer Biomet Spine, Inc., with the consent of the other defendants, removed this action to federal court pursuant to 28 U.S.C. § 1446(b) on April 7, 2023.

After Defendants moved to dismiss the initial complaint, [29], [32], Plaintiffs filed an amended complaint, [33]. Plaintiffs amended the complaint two more times, and Defendants moved to dismiss each amended complaint. [38], [48], [49], [72], [74].

In the TAC, [84], filed on January 23, 2024, Plaintiffs assert the following claims: against the Rush Defendants, Plaintiffs allege medical negligence, lack of informed consent, and loss of consortium; against ZimVie, Inc. and Zimmer Biomet Spine, Inc., Plaintiffs assert product liability (strict liability for unreasonable dangerous product, strict liability for failure to warn, and negligent design) and loss of consortium; and against Healthwerks, Inc., Corsi, and Clark, Plaintiffs allege claims of product liability (strict liability for failure to warn and negligence), loss of consortium, and negligence. Plaintiffs also assert a joint venture claim against Rush University Medical Center, ZimVie, Inc., Zimmer Biomet Spine, Inc., and Healthweks, Inc. Finally, Plaintiffs allege *res ipsa loquitor* as to all Defendants.

The Rush Defendants answered most counts of the TAC, [90], [91], [92], but moved to dismiss Counts XX and XXII, [93], and the Manufacturer and Distributor Defendants moved to dismiss all claims asserted against them, [96].[1]

II. Legal Standard

Defendants move to dismiss Plaintiffs' TAC under Rule 12(b)(6) of the Federal Rules of Civil Procedure. To survive a 12(b)(6) motion, a complaint must include a

[1] Plaintiffs subsequently sought leave to file a Fourth Amended Complaint, which the Court granted over objection. [114], [116]. After Plaintiffs filed their Fourth Amended Complaint, [117], Defendants moved to strike the Fourth Amended Complaint, [118], [119]. The Court granted that motion and reinstated the TAC and Defendants' motions to dismiss the TAC. [130].

"short and plain statement of the claim" showing that the pleader merits relief, Fed. R. Civ. P. 8(a)(2), and provide "fair notice" of the claim and "the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). The complaint must "state a claim to relief that is plausible on its face." *Yeftich v. Navistar, Inc.,* 722 F.3d 911, 915 (7th Cir. 2013) (quoting *Twombly*, 550 U.S. at 579).

For a claim to have facial plausibility, a plaintiff must plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). While the factual allegations required to state a plausible claim for relief depend upon the complexity of the case, threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, will not suffice. *Limestone Development Corp. v. Village of Lemont*, 520 F.3d 797, 803–04 (7th Cir. 2008). The Court construes the complaint in the light most favorable to Plaintiff, accepts as true all well-pleaded facts, and draws all reasonable inferences in her favor. *Yeftich*, 722 F.3d at 915; *Bonte v. U.S. Bank, N.A.*, 624 F.3d 461, 463 (7th Cir. 2010). The Court need not accept statements of law as true. *Yeftich*, 722 F.3d at 915.

On a motion to dismiss, this Court considers the "allegations set forth in the complaint itself, documents that are attached to the complaint, documents that are central to the complaint and are referred to in it, and information that is properly subject to judicial notice." *Williamson v. Curran*, 714 F.3d 432, 436 (7th Cir. 2013).

A court can properly take judicial notice of any fact that "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned," Fed. R. Civ. P. 201(b)(2), which includes public records and agency determinations. *Henson v. CSC Credit Servs.*, 29 F.3d 280, 284 (7th Cir. 1994); *Fornalik v.* Perryman, 223 F.3d 523, 529 (7th Cir. 2000). In a medical device preemption case, the Court may take judicial notice of PMA approval through publicly available FDA determinations on the agency website. *See Vincent v. Medtronic, Inc.*, 221 F. Supp. 3d 1005, 1007 (N.D. Ill. 2016).

III. Analysis

Defendants move to dismiss Plaintiffs' joint venture and *res ipsa loquitur* claims for failure to state a claim. The Distributor Defendants argue the same for Plaintiffs' negligence claims against the Healthwerks sales representatives. The Manufacturer and Distributor Defendants additionally argue that federal law preempts Plaintiffs' claims, and the Distributor Defendants assert that the Illinois Distributor Statute prohibits the Plaintiffs from asserting product liability claims against them. The Court considers the parties' arguments below, starting with preemption.

A. Preemption of Claims against Manufacturer and Distributor

The Manufacturer and Distributor Defendants argue that the MDA explicitly and implicitly preempts Plaintiff's state-law product liability and negligence claims. Plaintiffs respond that, as an affirmative defense, preemption remains inappropriate

at the motion to dismiss stage, and, alternatively, that their claims concern the inserter of the Mobi-C device which falls outside the MDA preemption clause. This section addresses each argument in turn.

1. Preemption as an Affirmative Defense

Plaintiffs argue that a preemption challenge remains inappropriate at this stage, since preemption operates as an affirmative defense. [103] at 7. Not so. While plaintiffs "need not anticipate or attempt to circumvent affirmative defenses," *Bausch v. Stryker Corp.*, 630 F.3d 546, 561 (7th Cir. 2010), defendants may assert an affirmative defense, including preemption, in a motion to dismiss. *See Gravitt v. Mentor Worldwide, LLC*, 289 F. Supp. 3d 877, 884 (N.D. Ill. 2018) (collecting cases). So long "it is plain from the complaint that the defense is indeed a bar to the suit," "dismissal is proper without further pleading." *Jay E. Hayden Foundation v. First Neighbor Bank, N.A.*, 610 F.3d 382, 383 (7th Cir. 2010); *see also Independent Trust Corp. v. Stewart Information Services Corp.*, 665 F.3d 930, 935 (7th Cir. 2012) ("When a plaintiff's complaint nonetheless sets out all of the elements of an affirmative defense, dismissal under Rule 12(b)(6) is appropriate."). Therefore, this Court will consider the Manufacturer and Distributor Defendants' Motion to Dismiss based upon preemption grounds.

2. Preemption Under the MDA

In 1938, Congress passed the Federal Food, Drug, and Cosmetic Act. *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86, 87–88 (1964). Federal law did not

regulate medical devices, however, until the passage of the Medical Device Amendments of 1976 ("MDA"). *Riegel*, 552 U.S. at 315. With the MDA, Congress shifted the regulation of medical devices from the traditional State regime to a new regulatory structure that categorized and regulated devices based upon the risks imposed to the public. *Id.* The MDA includes an express preemption clause restricting States from imposing additional or different requirements for medical devices than those imposed by the MDA:

> No State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). States may only provide a traditional damages remedy for a common-law violation "when those duties parallel federal requirements." *Bausch v. Stryker Corp.*, 630 F.3d 546, 551 (7th Cir. 2010) (quoting *Lohr*, 518 U.S. at 495); *see also Riegel*, 552 U.S. at 325 ("State tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect.").

To assess whether preemption applies, a court must evaluate: (1) whether the FDA has established specific federal requirements for a particular device; (2) whether there exists particular state requirements for that medical device; and (3) whether these state requirements act different from or in addition to the specific federal requirements. *See Riegel*, 552 U.S. at 321–22. If the state claim creates different or

additional requirements, then § 360k(a) preempts the claim. *Id.* at 321.

As described *supra* in Part I.A., the FDA approved Mobi-C through the PMA process. The Supreme Court in *Riegel* held that premarket approval "imposes 'requirements' under the MDA" since "premarket approval is specific to individual devices." *Riegel*, 552 U.S. at 322–23; *see also McMullen v. Medtronic, Inc.*, 421 F.3d 482, 487–88 (7th Cir. 2005) (citing *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997)). Common-law and state-law causes of action for negligence and strict liability "do impose requirements" for the purposes of MDA preemption. *Riegel*, 552 U.S. at 323–24. As a result, the MDA preempts Plaintiffs' claims if these state-law requirements differ from, or add to, the FDA requirements.

Plaintiffs argue that their state-law claims run parallel to the FDA requirements because the claims impose no additional or different requirements on Mobi-C. Both the Manufacturer and Distributor Defendants face product liability, that is, strict liability for failure to warn charges based upon the same allegations. Plaintiffs claim the existing warnings were "insufficient to alert plaintiff and Plaintiff's physicians as to risk of adverse events and/or reactions," contained misleading warnings about the efficacy of the Inserter, failed to disclose inadequate testing, did not include post-marketing warnings, and instructions did not alter consumers to dangers posed. [84] ¶¶ 228, 229, 251, 252. Plaintiffs' TAC, however, does not assert that Defendants failed to provide the FDA-required warnings. *See id.* ¶¶ 225–34, 248–58. Plaintiffs' desired warnings, then, would constitute an addition

to the warnings that the FDA approved and required. A finding of liability requiring Defendants to conform to state-law failure to warn requirements, therefore, would reflect "a requirement 'different from, or in addition to,' the standard required by federal authority." *Mitchell*, 126 F.3d at 913. Plaintiffs' failure to warn claim thus remains preempted.

Plaintiffs also assert a claim alleging product liability, that is, strict liability for unreasonably dangerous product against the Distributor Defendants. Plaintiffs allege that "the Implant Inserter" of the Mobi-C device "was in an unreasonably dangerous and defective condition" based upon its design, lack of testing, and the risk imposed. [84] ¶ 218. This claim also remains preempted because the FDA approval incorporated the inserter's design, testing, intended use, manufacturing methods, performance standards, and labeling. *See infra* Part III.A.3. The FDA thus already determined that Mobi-C and its inserter's "approved form provides a reasonable assurance of safety and effectiveness." *Riegel*, 552 U.S. at 323; *see also Mitchell*, 126 F.3d at 913 (finding product liability claim that Class III medical device was "an unreasonably dangerous product" was preempted because through PMA process the FDA approved "product's design, testing, intended use, manufacturing methods, performance standards and labeling").

Likewise, Plaintiffs' product liability "negligent design" claim against the Manufacturer Defendants fails for the same reason. Plaintiffs' TAC does not challenge the FDA-approved design and does not allege a manufacturing defect nor

inconsistency with the PMA process. *Cf Bausch v. Stryker Corp.*, 630 F.3d 546, 552 (7th Cir. 2010) (noting preemption did not apply where "state law claim" was "based on manufacturing defect resulting from violation of FDA requirements" or if negligence claim was "based on claims that manufacturer did not adhere to FDA standards in the premarket approval process")(citing *Chamber v. Osteonics Corp.*, 109 F.3d 1243, 1248 (7th Cir. 1997); *Mitchell*, 126 F.3d at 913 n.6).

Finally, Plaintiffs' product liability "negligence" claims do not allege that the distributors failed to comply with FDA requirements. Instead, the allegations state that the distributors should have conformed with state-law requirements *in addition* to FDA requirements. [84] ¶¶259–63. That claim also remains preempted.

3. Whether the Mobi-C Inserter is Subject to Preemption

As a Class III device, the Mobi-C device remains subject to preemption under the MDA. 21 U.S.C. § 360k(a). Plaintiffs argue that their claims concern the Mobi-C Universal Inserter/Implant Inserter, a separate instrument from the Mobi-C "device." [84] ¶¶ 69, 101. In their view, preemption remains inapplicable because the inserter qualifies as a Class I device, separate and apart from the Mobi-C device. [84] ¶ 89. Whether the inserter functions as part of the PMA-approved Mobi-C device or qualifies as an independently-approved separate device constitutes a proper question of law since the determination requires statutory and regulatory interpretation. *See Daley v. Teruel*, 107 N.E.3d 1028, 1035 (Ill. App. Ct. 2018).

In the context of medical devices, the FDA defines "device" as an "instrument,

apparatus, implement," or "implant," "including any component, part, or accessory." 21 U.S.C. § 321(h). FDA regulations further define "component" as "any" "piece, part," "or assembly that is intended to be included as part of the finished, packaged, and labeled device." 21 C.F.R. § 820.3(a). A "finished device means any device or accessory to any device that is suitable for use or capable of functioning." *Id.* Based upon these definitions, "courts have held that once a device as a whole receives PMA approval, the MDA preempts non-parallel state law claims directed at, not only the device as a whole, but also at the device's component parts." *In re Smith & Nephew BHR Hip Implant Products Liability Litigation* (*BHR Hip*), 401 F. Supp. 3d 538, 552 (D. Md. 2019) (citing to *Kubicki v. Medtronic, Inc.*, 293 F. Supp. 3d 129, 174–76 (D.C.C. 2018)); *see also id.* at n.3 (collecting cases).

Plaintiffs rely upon *BHR Hip* for a device component not subject to preemption based upon its approval under § 510(k). In *BHR Hip*, the plaintiff alleged injury from two medical devices: "the BHR-THA system" and the "R3-THA system." *Id.* at 547. Each device constituted a "hybrid" system, in that one part of the system received PMA approval, but the other parts completed the § 510(k) process. *Id.* at 551 ("The BHR cup in the BHR-THA system and the R3 metal liner in the R3-THA system received PMA approval, but the remaining elements of both systems were approved through the § 510(k) process."). After reviewing relevant case law, statutes, and FDA briefings on the subject, the court in *BHR Hip* concluded that although "§ 360k(a) preempts non-parallel state-law claims that target premarket-approved

components," "it does not govern state-law claims that target a hybrid system's § 510(k) components or the system as a whole." *Id.* at 554. In other words, any PMA-approved component for each system remained subject to preemption (the BHR cup and R3 metal liner), but since the "hybrid systems" used parts that had not been part of the PMA process, each overall "hybrid system" did not enjoy MDA preemption. *Id.*

But this case differs from *BHR Hip*. Here, the FDA granted PMA approval to the entire Mobi-C device, which included the inserter. [84] ¶ 68 ("The components of the Mobi-C® include" "an ultra-high molecular weight polyethylene (UHMWPE per ISO 5834-2) *mobile insert*." (emphasis added)). The FDA-approved description of the Mobi-C device explicitly refers to "an ultra-high molecular weight polyethylene (UHMWPE per ISO 5834-2) mobile insert," and PMA supplement approvals explicitly authorize modifications to the inserter. [84] ¶ 68; [97-3] at 2–4 ("approval for modifications made to the Mobi-C universal inserter instrument"). The FDA definitions of "device" further support that the Mobi-C inserter functions as a "component" of Mobi-C and therefore constitutes part of the device. *See* 21 U.S.C. § 321(h); 21 C.F.R. § 820.3(a). In contrast to the "hybrid systems" discussed in *BHR Hip*, the entire Mobi-C device, including its inserter, remained subject to the PMA process and thus enjoys MDA preemption. *BHR Hip*, 401 F. Supp. 3d at 554. The Court thus grants the Manufacturer and Distributor Defendants' motion to dismiss as to Counts IX–XV.

B. Illinois Product Liability Distributor's Law

The Distributor Defendants argue that, even if preemption did not apply, Plaintiffs' product liability claims remain foreclosed by the Illinois "Distributor Statute." The statute provides that, once the manufacturer has been joined as a defendant in a product liability case, any named distributor defendants should be dismissed. 735 Ill. Comp. Stat. § 5/2-621 (2004). Exceptions to this rule exist, however, and the distributors may remain in the case if the plaintiff can show that: "(1) the defendant has exercised some significant control over the design or manufacture of the product, or has provided instructions or warnings to the manufacturer relative to the alleged defect in the product which caused the injury, death, or damage;" "(2) the defendant had actual knowledge of the defect;" or "(3) the defendant created the defect." *Id.* Despite its procedural nature, the law functions as outcome-determinative, and courts thus have applied it in federal court. *Ungaro v. Rosalco, Inc.*, 948 F. Supp. 783, 785 (N.D. Ill. 1996) (citing *Farris v. Satzinger G.M.B.H. & Co.*, 681 F. Supp. 485, 488 (N.D. Ill. 1987)). The rule only applies to product liability claims against distributors; general negligence claims do not fall under the statute. *Caterpillar, Inc. v. Usinor Industeel*, 393 F. Supp. 2d 659, 684–85 (N.D. Ill. 2005); *Whelchel v. Briggs & Stratton Corp.*, 850 F. Supp. 2d 926, 936 (N.D. Ill. 2012).

Plaintiffs assert two product liability claims against Healthwerks: failure to warn and negligence. ZimVie and Zimmer Biomet Spine, the manufacturers of Mobi-

C and the inserter, remain parties to this litigation. Based upon Illinois' Distributor Statute, Plaintiffs' product liability claims against the distributors, Healthwerks, Corsi, and Clark, must be dismissed unless an exception applies. Plaintiffs do not claim that Healthwerks played any role, or exercised any control, in manufacturing; nor do they allege that Healthwerks knew about or created the alleged defect. Additionally, nothing in the complaint suggests that Healthwerks failed to provide the FDA-mandated warnings; the claims arise because the Distributors allegedly failed to provide *additional* warnings about the product and its potential harm. [84] ¶¶ 252, 261. In short, nothing in the TAC supports the existence of an exception under the Illinois Distributors Statute. As a result, even in the absence of preemption, Plaintiffs' product liability claims against the Distributors Defendants must be dismissed.

C. Negligence Claims Against Clark and Corsi

Plaintiffs allege negligence against Clark and Corsi, the Healthwerks sales representatives present at Miller's surgery. The MDA does not preempt these claims since the FDA does not regulate on-site sales representatives who interact with physicians at a surgery, *Medtronic, Inc. v. Malander*, 996 N.E.2d 412, 419 (7th Cir. 2013) (citing *Adkins v. Cytyc Corp.*, No. 4:07CV00053, 2008 WL 2680474, at *3 (W.D. Va. Jul. 3, 2008)), and the Illinois Distributors statute does not affect general negligence claims. *Whelchel v. Briggs & Stratton Corp.*, 850 F. Supp. 2d 926, 936 (N.D. Ill. 2012).

A negligence claim will survive a motion to dismiss if the plaintiff pleads sufficient facts that "the defendant owed a duty to the plaintiff, that the defendant breached that duty, and that the breach was the proximate cause of the plaintiff's injury." *Quiroz v. Chicago Transit Authority*, 211 N.E.3d 437, 442 (Ill. 2022) (quoting *Krywin v. Chicago Transit Authority*, 938 N.E.2d 440 (Ill. 2010)). Whether a duty exists remains a question of law appropriate for the Court to decide. *Aquino v. C.R. Bard, Inc.*, 413 F. Supp. 3d 770, 792 (N.D. Ill. 2019) (citing *Neumann v. Borg-Warner Morse Tec LLC*, 168 F. Supp. 3d 1116, 1120 (N.D. Ill. 2016)). In Illinois, "every person owes a duty of ordinary care to all others to guard against injuries which naturally flow as a reasonably probable and foreseeable consequence of an act, and such a duty does not depend upon contract, privity of interest or the proximity of relationship, but extends to remote and unknown persons." *Doe-3 v. McLean County Unit District Number 5 Board of Directors*, 973 N.E.2d 880, 887–88 (Ill. 2012) (quoting *Simpkins v. CSX Transportation, Inc.*, 965 N.E.2d 1092 (Ill. 2012)). Therefore, "where a defendant's course of action creates a foreseeable risk of injury, the defendant has a duty to protect others from such injury." *Id.* at 888.

Defendants argue that, as sales representatives, Clark and Corsi have no duty to a patient, even if they attend the patient's surgery. In fact, the FDA documents providing instructions and warnings for use of the Mobi-C device explicitly address physicians only and do not mention any role for a sales representative during surgery. [103-3] at 32. The approved use of the Mobi-C device requires no involvement by a

sales representative and imposes no duty between the sales representatives and a patient. *Cf Westmoreland v. Medtronic, Inc.*, No. 4:17-CV-01626-AGF, 2017 WL 5132669, at *3 (E.D. Mo. Nov. 6, 2017).

If a sales representative, however, takes part in the surgery by assisting in some way, he may assume a voluntary duty to the patient to act with reasonable care. *See Avila v. Chicago Transit Authority*, 187 N.E.3d 136, 148 (Ill. App. Ct. 2021) ("Under a voluntary undertaking theory of liability, a party who undertakes to perform an action or render a service to another is liable for injuries caused by that party's failure to exercise due care in the performance of the undertaking.") (citing *Rhodes v. Illinois Central Gulf R.R.*, 665 N.E.2d 1260 (1996)). Illinois courts construe such voluntary duty "narrowly, and the duty of care imposed upon a party is strictly limited to extent of the undertaking." *Id.* (citing *Elam v. O'Connor & Nakos, Ltd.*, 142 N.E.3d 393 (Ill. App. Ct. 1996)).

Whether a defendant has voluntarily assumed a duty remains a question of law for the court. *Id.* (citing *Jakubowski v. Alden-Bennett Construction Co.*, 763 N.E.2d 790 (2002)). When a defendant voluntarily acts, the defendant becomes "subject to a duty with respect to the manner of performance." *Bell v. Hutsell*, 955 N.E.2d 1099, 1107 (Ill. 2011) (quoting *Wakulich v. Mraz,* 785 N.E.2d 843 (Ill. 2003)). Not all actions or representations create a voluntary duty; courts often look for where "there were affirmative acts taken by defendant and allegations of negligent performance of those undertakings." *See Stephen v. Swiatkowski*, 635 N.E. 2d 997,

1005 (Ill. App. Ct. 1994). Foreseeability of an injury does not alone create a legal duty; a court should also consider "the relationship between defendant and plaintiff, the likelihood of injury, the magnitude of guarding against the injuries, and the consequences of placing that burden on defendant." *Dorge v. Martin*, 905 N.E.2d 327, 332 (Ill. App. Ct. 2009).

Plaintiffs allege that Clark and Corsi failed to undergo adequate training on the use of the Implant Inserter before attending Miller's surgery; improperly set up or loaded the Implant Inserter; failed to proper assemble the Implant Inserter prior to the procedure; and failed to verify that the Implant Inserter was properly assembled before allowing the surgical team to use it in Miller's surgery. [84] ¶¶ 276, 292. If Clark or Corsi assembled the inserter for the Mobi-C device or otherwise participated in Miller's surgery, such action could constitute an affirmative role in Miller's surgery. And if, having undertaken an affirmative role in the surgery, either Defendant failed to use reasonable care, they plausibly could have created a foreseeable possibility that the inserter, an essential instrument in the surgery, could injure the unconscious Miller. Therefore, at this stage of the proceedings, Plaintiffs have sufficiently pled that Clark and Corsi had a duty to act with reasonable care to Miller during the surgery. *See Dorge*, 905 N.E.2d at 332 (holding where "someone voluntarily undertakes a duty, she must perform the duty with due care or with such competence and skill as the volunteer possesses.") (citing *Poelker v. Macon Community Unit School District Number 5*, 571 N.E.2d 479, 480 (Ill. App. Ct. 1990)).

Additionally, Plaintiffs' allegations sufficiently plead that the sales representatives failed to act with reasonable care by improperly assembling the inserter. Finally, Plaintiffs sufficiently allege that Miller's injury, caused by a failure of the Mobi-C device, remains proximately caused by Clark or Corsi's negligence.

Accordingly, the Court denies the Distributor Defendants' motion to dismiss Counts XVI and XVIII.

D. *Res Ipsa Loquitur*

Though not a separate cause of action, r*es ipsa loquitur* acts as an "evidentiary rule" that "allows an inference of negligence to be drawn from a certain set of facts." *Newell v. Westinghouse Elec. Corp.*, 36 F.3d 576, 578 (7th Cir. 1994) (internal citation omitted); *see also Krivokuca v. City of Chicago*, 73 N.E.3d 525, 532 (Ill. App. Ct. 2017) (quoting *Collins v. Superior Air-Ground Ambulance Service, Inc.*, 789 N.E.2d 394 (Ill. 2003)). Plaintiffs need not plead *res ipsa loquitur* to invoke the theory in court, but plaintiffs may separately plead *res ipsa loquitur* "primarily to give notice" to defendants. *See Guzman v. Target Corp.*, No. 18-cv-4508, 2018 WL 5977924, at *4 (N.D. Ill. Nov. 14, 2018) (quoting *Belknap v. Ford Motor Co.*, No. 03-c-50125, 2003 WL 21781890, at *3 (N.D. Ill. July 30, 2003)). If pled, defendants may challenge the *res ipsa loquitur* claim in a motion to dismiss. *Heastie v.* Roberts, 877 N.E.2d 1064, 1076 (Ill. 2007) (collecting cases). Whether or not plaintiffs proper plead a *res ipsa loquitur* claim constitutes a question of law for the court to decide. *See id.* at 1075. Since *res ipsa loquitur* functions as a theory of negligence, a plaintiff must show that

the alleged tortfeasor owed a duty of care to the plaintiff. *Pearson v. Pilot Travel Centers, LLC*, 165 N.E.3d 9 (Ill. App. Ct. 2020). Illinois courts have applied *res ipsa loquitur* in medical malpractice cases. *Kolakowski v. Voris*, 415 N.E.2d 397 (Ill. 1980).

A plaintiff may invoke *res ipsa loquitur* upon a showing that "he was injured (1) in circumstances that ordinarily would not occur absent negligence," and "(2) by an agency or instrumentality within the defendant's management or control." *Smith v. United States*, 860 F.3d 995, 998 (7th Cir. 2017). In a medical malpractice suit, "proof of an unusual, unexpected or untoward medical result which ordinarily does not occur in the absence of negligence will suffice in the application of the doctrine." 735 Ill. Comp. Stat. 5/2-1113; *see also Peterson v. Hinsdale Hosp.*, 599 N.E.2d 84, 89 (Ill. App. Ct. 1992). Plaintiffs can show that the particular result would not occur absent negligence "either by presenting expert testimony to that effect, or by showing that the negligence was so grossly apparent that it falls within the common knowledge of non-medical persons." *Piquette v. Midtown Anestesia Associates*, 548 N.E.2d 659, 662 (Ill. App. Ct. 1989).

As to the second element, Illinois courts define "control" flexibly. *Smith*, 860 F.3d at 1000. But allegations that "the defendant has the right or power of control, and the opportunity to exercise it" suffice. *McGuckin v. Chicago Union Station*, 548 N.E.2d 461, 472 (Ill. App. Ct. 1989) (quoting W. Prosser & W. Keeton, Torts § 39, at 250 (5th ed. 1984)). Accordingly, "it is enough that the defendant is under a duty

which he cannot delegate to another." *Id.* In a case where "the plaintiff was unconscious at the time of the injury, and under the defendants' control, then the plaintiff has adequately shown the control element for *res ipsa loquitur*, even if she cannot establish the exact instrumentality that caused the injury." *Willis v. Morales*, 169 N.E.3d 74, 81–82 (Ill. App. Ct. 2020) (citing *Spidle v. Steward*, 402 N.E.2d 216 (Ill. App. Ct. 1980)).

A plaintiff may assert *res ipsa loquitur* against multiple defendants, but only if the plaintiff sues all those who might have caused the injury. *Colbert v. City of Chicago*, 851 F.3d 649 (7th Cir. 2017) (applying Illinois law). If several possible explanations for the injury exist, and the plaintiff cannot prove a particular defendant's actions caused the injury, then *res ipsa loquitur* cannot apply. *Napoli v. Hinsdale Hospital*, 572 N.E.2d 995, 999 (Ill. App. Ct. 1991).

Here, the allegations sufficiently plead facts to invoke *res ipsa loquitur*. First, Plaintiffs allege negligence claims against the Rush Defendants and Clark and Corsi, which all survive the Defendants' motions to dismiss, and the complaint contains sufficient facts to support that Miller's injury from the depth stop failure would not have occurred without negligence by the Defendants. [84] ¶ 305. The Rush Defendants argue that, since the surgery included inherent risks, the injury plausibly could have occurred even in the absence of any negligence. But this argument turns upon matters beyond the TAC (including an evaluation of the nature of the surgery, the extent of the risks assumed, etc.) and thus remains inappropriate at this stage of

the litigation. *See Miller v. Herman*, 600 F.3d 726, 733 (7th Cir. 2010).

Additionally, Plaintiffs need not prove that Defendants had exclusive control of the instrumentality causing the injury. The Rush Defendants argue that *res ipsa loquitur* cannot apply because Plaintiffs allege fault by several different defendants, and it remains uncertain whose action (and control) caused the injury. [103] at 2–6; [110] at 2–4. In making this argument, Defendants cite *Raleigh v. Alcon Laboratories, Inc.*, 934 N.E.2d 530 (Ill. App. Ct. 2010) and *Metz v. Central Illinois Elec. & Gas Co.*, 207 N.E.2d 305 (Ill. 1965), which concerned a motion for summary judgment and post-trial motions. Again, at this stage, Plaintiffs need only articulate plausible facts to support the claim. Plaintiffs allege that Defendants each had control of the inserter at some point, and that they each owed a duty of care when they exercised such control. *See McGuckin*, 548 N.E.2d at 472. That Miller remained unconscious during the surgery, himself under Defendants' control, further bolsters the sufficiency of the allegations at this stage. *See Willis v. Morales*, 169 N.E.3d at 81–82. The Court thus denies the Defendants' motions to dismiss Plaintiffs' *res ipsa loquitur* count as to the surviving negligence claims.

E. Joint Venture

In Count XXII, Plaintiffs allege that Rush, Healthwerks, and the Manufacturing Defendants formed a joint venture, an association "to carry out a single business enterprise for profit." *The Majestic Star Casino, LLC v. Trustmark Ins. Co.*, 667 F. Supp. 2d 809, 819 (N.D. Ill. 2009) (citing *Barton v. Evanston Hosp.*,

513 N.E.2d 65 (Ill. App. Ct. 1987)). To plead a joint venture, a plaintiff must allege "(1) an express or implied agreement to carry on an enterprise; (2) a demonstration of intent to be joint venturers; (3) a community of interest, as reflected in the contribution of property, money, effort, skill, or knowledge; (4) a measure of joint control and management of the enterprise; and (5) sharing of profits and losses." *Hiatt*, 36 N.E.3d at 865–66 (citing *Fitchie v. Yurko*, 570 N.E.2d 892 (Ill. App. Ct. 1991)). The most significant factor in determining the existence of a joint venture remains whether the parties intended to create a joint venture. *O'Brien v. Cacciatore*, 591 N.E.2d 1384, 1384 (Ill. App. Ct. 1992). A joint venture need not be established through a formal agreement; the existence "may be inferred from the facts and circumstances demonstrating that the parties in fact entered into a joint venture." *Id.* at 1384. The party claiming that the joint venture exists bears the burden to prove its existence. *Id.* at 1389. Although typically a question of fact, a court may determine the issue of joint venture as a matter of law "where there is no evidence to support the existence of a joint venture." *Andrews v. Marriot International, Inc.*, 61 N.E.3d 1105, 1114 (Ill. App. Ct. 2016).

Plaintiffs do not allege a formal joint venture agreement or plead sufficient facts to support the existence of an inferred joint venture agreement. Plaintiffs state that Defendants shared in profits based upon the fee structure between Rush and the Manufacturers and the Distributor, where the Manufacturers "were required to bill the hospital $4,275 for the purchase of" the Mobi-C device, "Distributors charge 20%

of the purchase price for the sale of the device," and Rush billed Plaintiff and/or his insurer $16,287.75 for the device. [84] ¶¶ 318, 319, 322, 327. This alleged fee structure, however, suggests a typical supply chain agreement between separate business entities and does not require the entities to share in the losses. *Cf. Andrews*, 61 N.E.3d at 1116–17 ("Two businesses entering into a service agreement 'seeking to mutually profit from it' is not enough to turn a business relationship into a joint venture . . . .") (quoting *Kaporovskiy v. Grecian Delight Foods, Inc.*, 787 N.E.2d 268, 212 (Ill. App. Ct. 2003)). Additionally, the storage of Mobi-C devices at Rush and the presence of sales representatives at surgery suggest nothing more than convenient logistical arrangements and standard product support, even in the light most favorable to Plaintiffs. *See id.*; [84] ¶¶ 320–21. Plaintiffs allege no facts to suggest that Defendants agreed or intended to act as an enterprise, shared a community of interest, or exercised joint control over the enterprise. Because Plaintiffs' Complaint does not support the required elements of a joint venture, the Court grants Defendants' motions to dismiss Count XXII.

IV. Conclusion

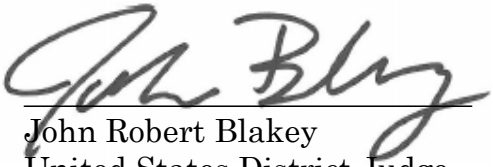
For the reasons explained above, this Court grants in part, and denies in part, Defendants' motions to dismiss, [93], [96]. More specifically, the Court grants the Rush Defendants' motion to dismiss the joint venture claim (Count XXII) but denies the motion as to the *res ipsa loquitur* claim (Count XX); grants the Manufacturer Defendants' motion as to all claims asserted against them and dismisses the

Manufacturer Defendants from the case; and grants the Distributor Defendants' motion as to the product liability claims (Counts XIII–XIV), and the joint venture claim (Count XXII), but denies the motion as to Plaintiffs' negligence claims (Counts XVI, XVIII) and *res ipsa loquitur* claim (Count XX). The Court also dismisses Plaintiffs' loss of consortium claims derived from the dismissed counts (Counts XII, XV). *Webber v. Armslist LLC*, 70 F.4th 945, 965 (7th Cir. 2023) (affirming dismissal of loss of consortium claims where no underlying tort existed for the claims).

Defendants shall answer the TAC by February 20, 2026, and the parties shall file a joint status report by February 27, 2026, proposing reasonable case management dates. The parties should call chambers if they all agree that a settlement conference could be helpful, and the Court will enter an appropriate order.

Date: January 20, 2026

ENTERED:



John Robert Blakey
United States District Judge